

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
 (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

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| Applicant's or agent's file reference FP05-0011-00 | FOR FURTHER ACTION | | See item 4 below |
| International application No. PCT/JP2005/001355 | International filing date (<i>day/month/year</i>) 31 January 2005 (31.01.2005) | Priority date (<i>day/month/year</i>) 30 January 2004 (30.01.2004) | |
| International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237 | | | |
| Applicant HISAMITSU PHARMACEUTICAL CO., INC. | | | |

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

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|-------------------------------------|--------------|---|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the report |
| <input type="checkbox"/> | Box No. II | Priority |
| <input type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input type="checkbox"/> | Box No. VIII | Certain observations on the international application |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

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| | Date of issuance of this report 22 August 2006 (22.08.2006) |
| The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 338 82 70 | Authorized officer Masashi Honda e-mail: pt08@wipo.int |

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

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| To: |
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PCT
TRANSLATION

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

(PCT Rule 43bis.I)

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|---|---|---|
| Applicant's or agent's file reference FP05-0011-00 | | Date of mailing (day/month/year) |
| International application No. PCT/JP2005/001355 | International filing date (day/month/year) 31.01.2005 | Priority date (day/month/year) 30.01.2004 |
| International Patent Classification (IPC) or both national classification and IPC | | |
| Applicant HISAMITSU PHARMACEUTICAL CO., INC. | | |

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| <p>1. This opinion contains indications relating to the following items:</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Rule 43bis.I(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application <p>2. FURTHER ACTION</p> <p>If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.</p> <p>If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.</p> <p>For further options, see Form PCT/ISA/220.</p> <p>3. For further details, see notes to Form PCT/ISA/220.</p> |
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| Name and mailing address of the ISA/JP | Authorized officer |
| Facsimile No. | Telephone No. |

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2005/001355

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).
2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material
 a sequence listing
 table(s) related to the sequence listing
 - b. format of material
 in written format
 in computer readable form
 - c. time of filing/furnishing
 contained in the international application as filed.
 filed together with the international application in computer readable form.
 furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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| International application No. |
| PCT/JP2005/001355 |

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| Box No. V | | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>1. Statement</p> <table> <tr> <td align="center">Novelty (N)</td> <td>Claims</td> <td><u>1-10</u></td> <td align="center">YES</td> </tr> <tr> <td></td> <td>Claims</td> <td>_____</td> <td align="center">NO</td> </tr> <tr> <td align="center">Inventive step (IS)</td> <td>Claims</td> <td>_____</td> <td align="center">YES</td> </tr> <tr> <td></td> <td>Claims</td> <td><u>1-10</u></td> <td align="center">NO</td> </tr> <tr> <td align="center">Industrial applicability (IA)</td> <td>Claims</td> <td><u>1-10</u></td> <td align="center">YES</td> </tr> <tr> <td></td> <td>Claims</td> <td>_____</td> <td align="center">NO</td> </tr> </table> | | | Novelty (N) | Claims | <u>1-10</u> | YES | | Claims | _____ | NO | Inventive step (IS) | Claims | _____ | YES | | Claims | <u>1-10</u> | NO | Industrial applicability (IA) | Claims | <u>1-10</u> | YES | | Claims | _____ | NO |
| Novelty (N) | Claims | <u>1-10</u> | YES | | | | | | | | | | | | | | | | | | | | | | | |
| | Claims | _____ | NO | | | | | | | | | | | | | | | | | | | | | | | |
| Inventive step (IS) | Claims | _____ | YES | | | | | | | | | | | | | | | | | | | | | | | |
| | Claims | <u>1-10</u> | NO | | | | | | | | | | | | | | | | | | | | | | | |
| Industrial applicability (IA) | Claims | <u>1-10</u> | YES | | | | | | | | | | | | | | | | | | | | | | | |
| | Claims | _____ | NO | | | | | | | | | | | | | | | | | | | | | | | |
| <p>2. Citations and explanations:</p> <p>Document 1: WO, 02-38097, A (Johnson & Johnson Medical Limited), 16 May, 2002 (16.05.02), page 2, line 26-31, page 5, lines 4-11, page 10, lines 8-10, Figs. 1-2</p> <p>Document 2: JP, 8-92074, A (Nitto Denko Corp.), 9 April, 1996 (09.04.96), column 2, line 42 to column 3, line 41, column 6, lines 30-41, column 8, lines 46-47</p> <p>Document 3: JP, 2003-62058, A (Nitto Denko Corp.), 4 March, 2003 (04.03.03), column 1, lines 2-42, column 8, lines 33-39, column 9, lines 19-34</p> <p>The subject matters of claims 1-3, 5-8, and 10 do not appear to involve an inventive step in view of document 1 (page 2, line 26-31, page 5, lines 4-11, page 10, lines 8-10, Figs. 1-2) and document 2 (column 2, line 42 to column 3, line 41, column 6, lines 30-41, column 8, lines 46-47) cited in the ISR. A person skilled in the art could have easily conceived of using a drug or adhesive described in document 2, as a top sheet or a dressing having the top sheet described in document 1.</p> <p>The subject matters of claims 4 and 9 do not appear to involve an inventive step in view of document 1 and document 3 (column 1, lines 2-42, column 8, lines 33-39, column 9, lines 19-34) cited in the ISR. A person skilled in the art could have easily conceived of the point of using an adhesive that includes a plasticizer described in document 3 to the top sheet or the dressing having the top sheet described in document 1.</p> | | | | | | | | | | | | | | | | | | | | | | | | | | |